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Statement

Of

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(Safe Medicine Disposal for ME)

Before the DEA Public Meeting on safe and effective disposal of controlled substances from ultimate users and long term care facilities in reference to Public Law 111-273, the Secure and Responsible Drug Disposal Act of 2010 (S3397)

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Diversion of both controlled and non-controlled drugs is not just a common household trouble but a national problem and international as well. Unused medication presents a broad array of hazards and needs a proper resolution for safe and effective disposal to achieve the following:

1. To curtail childhood overdoses
2. To restrict household drug theft and subsequent illegal trafficking and use
3. To limit accumulation of drugs by the elderly
4. To protect our physical environment
5. To restrain improper international drug donations
6. To eliminate waste in the health care system across the country

There are five primary models for drug take-back programs. The first, a pharmacy based take back program, is the predominant method. Such disposal has been via return to pharmacies through variously funded systems. Pharmacy-based drop off's present a number of regulatory aspects that the Public Law 111-273 does not address. FDA regulations forbid the return of medication to pharmacy stocks. This not only includes prescribed unused medications, but also free samples provided by physician offices. Both represent a large quantity of medication that has been largely ignored by regulatory agencies in the past. However, federal EPA and State DEP regulations have some controlling regulations and have made recent attempts to address this problem.. The biggest problem with pharmacy-based (and most other) collection program is that of controlled substances. While there have been efforts across the country to have non-controlled drugs returned to pharmacies, the general public is often unaware of which drugs are and are not controlled. This has resulted in inadvertent collection of controlled substances, as well as intentional diversion, which has led to several prosecutions.

The second, drug take back events has immense duplicative infrastructure requirements. The DEA has built on the success of law enforcement controlled consumer drug take back events with the first National Take Back day in September 2010. While success was measured in tons, more can be done with cooperation across the country, particularly around identification of what is being wasted. While certainly having a positive impact, these types of take-back programs are erratically scheduled and variably available to the entire population. Continuing them however provides valuable community education, and generally uses community strength and resources to run them. Even so, more consistent and readily available programs are needed to effectively address this ubiquitous problem.

The third and fourth models- police drop boxes and pickups - have had variable success. Efforts to place drug return receptacles on police property will appeal to some, but not al,l citizens. In Caribou, Maine, the Chief of Police has instituted a policy whereby residents of the community need only pick up the phone and call and a cruiser will be sent to the resident's home, no questions asked, and their drugs will be taken into police custody and held for destruction. It is unlikely that the majority of police departments will view the Caribou model as fitting for them, even though they increase the immediacy of a solution over take back events.

The fifth model is a mail-back program. In 2007, the US EPA awarded a grant to study a mail-back process based in part the earlier passage of state law to codify enabling language for the Maine Drug Enforcement Agency to facilitate such programs. Agreements between the Maine Drug Enforcement Agency and the US DEA and the US Postal Service followed after extensive discussions, meetings, and testing of the envelopes to be used. Several verification methods were used to monitor for diversion, which has not to the best of our knowledge occurred. None has. In addition by using the Postal Service, inspectors were able to assess diversion independently. Recently, the suggestion to incorporate 2D barcode and/or RFID chips in the envelopes would permit even more secure tracking and tracing of envelopes. This technique could eventually meet the electronic tracking standards as specified by the 2007 FDA Amendment act, which specifies Unique Device Identification capability, following the FDA issuing it's Pharmaceutical Bar Code Rule in 2004. An opportunity exists to maintain product identity throughout the entire life-cycle of the drug including destruction, as well as ensure personal accountability for each pill.

The process of the Maine mail-back program is simple. Consumers pick up mailers at any of over 100 distribution sites across the State, including many pharmacies and some law enforcement agencies. Each envelope has inserts that include instructions on how to pack the medications and an optional brief questionnaire. Once filled and sealed, the postage-paid envelopes are simply dropped in the US Mail. The mail has a pre-printed delivery address which is controlled by the Maine Drug Enforcement Agency and is taken for storage in evidence until a sufficient quantity exists for destruction. With Maine's strict environmental regulations, the medications must be segregated by hand with controlled substances being incinerated in the State and the non-controlled medications being sent to costly out of state incinerators. It is not clear that the inter-state variability in destruction regulations will affect the practically or feasibility of national, regional, or state based mail-back programs, which leads to the major recommendation of my testimony. Mail programs offer immediacy. They are also amenable to a number of different funding methods for sustainability. Of the five general models of drug return, it remains the most accessible to the public, providing a way to dispose of unwanted medication without having to transport them any further than their own mailbox. Our recommendation is to enable state, regional, or national mail-back programs for accessibility to all citizens.

Mail-back also offers a solution to long term care facilities. We propose a special larger-scale mail-back program for them whereby what is being returned could be logged by the receiving site. This could be an additionally DEA credentialed reverse distributor or waste management company with special agreements to be included in the new proposed regulations. Manifests could be reported regularly, preferably in real time to the DEA, both from a trusted identity at the long term care facility and the destruction site.

Discussion of the relative costs of the various processes is somewhat premature, in that the proposed regulations could broaden the number of programs that offer mailers, either at a cost to the end user, to industry, or from public health improvement or crime reduction grants. Depending on their size, there may be a range of costs. However, the economies of scale advantage should apply as programs expand, reducing cost-per-envelope expenses. Our current cost with no volume discounts is less than most single drug co-pays. It does not restrict which drugs can be returned (notably controlled substances), and permits multiple containers per mailer, as well.

In closing, the unused medication that needs to be destroyed is the product of a number of individuals and interveners. It is the product of the pharmacist who dispenses the medications. It is the product of the prescriber, whether that is a physician, veterinarian, or other authorized health care worker. It is also the product of the payer, the insurance company, and all the other various entities that influence the drug-use process. Ultimately, it is the product of the manufacturer.

Approaches to preventing the problem in the first place are something to be considered in drafting the regulations. Only hard knowledge of what is being wasted and returned will help each of those producers improve or modify their practices. It is important to note that that knowledge has already changed policy in the State of Maine by requiring 15-day supply

maximum for a first prescription of over fifty different medications. CMS is proposing across the board even tighter short first-fills. They are also requiring drugs to be returned for counting from the long term care facilities in order to identify what is being wasted. We urge the DEA to include in the regulatory language that research and verification of product integrity be included in the final regulations. Finally, there is the need for a national Drug Disposal Center for coordinating information and education. The DEA would benefit from such an independent group as it faces the need to raise public awareness of what is authorized and what is not under the new regulations.

I am available for any questions or queries either now or in the future. Thank you for your time.

Attachments:

1. Previous submission to DEA
2. US Senate verbal testimony for S 3397
3. US Senate written for S 3397
4. Final US EPA Grant Report for CH-83336001-0